

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IAN GARNER,
MICHAEL L. DALRYMPLE, DONNA E. PRUNKARD,
and DONALD C. FOSTER
(5,639,940),

Junior Party,

v.

WILLIAM H. VELANDER,
WILLIAM N. DROHAN, HENRYK LUBOŃ,
and JOHN L. JOHNSON (DECEASED)
(08/443,184),

Senior Party.

Interference No. 104,242

MAILED
JAN 15 2002
PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER and TORCZON,
Administrative Patent Judges.

Per curiam.

DECISION ON RECONSIDERATION
(PURSUANT TO 37 C.F.R. § 1.640)

A. INTRODUCTION

Velandar requests reconsideration of a panel decision holding all of its involved claims unpatentable (Paper No. 118). The decision has been reconsidered, but relief from that decision is DENIED.

B. FINDINGS

1. On 16 August 2001, a panel of the board entered judgment against both parties with regard to all involved claims on the basis of unpatentability, 35 U.S.C. 103 (Paper No. 110).

2. All of Velander's involved claims were held to be unpatentable as a consequence of the granting of Garner's preliminary motion 2 (Paper No. 22).

3. Garner's preliminary motion 2 sought a holding of unpatentability for all of Velander's involved claims. Garner cited the following prior art:

a. "Behringer et al., Science, 245, pp. 971-973 (1989) (Garner Exhibit 33)" (Paper No. 22 at 12 ¶18).

b. "Burdon et al., J. Biol. Chem., 266, pp. 6909-6914 (1991) (Garner Exhibit 8)" (Paper No. 22 at 12 ¶18).

c. "Chung et al., Biochemistry, 22, pp. 3244-3250 (1983) (Garner Exhibit 23)" (Paper No. 22 at 7 ¶11).

d. "Chung et al., Biochemistry, 22, pp. 3250-3256 (1983) (Garner Exhibit 24)" (Paper No. 22 at 7 ¶11).

e. "Chung et al., Adv. Exp. Med. Biol., 281, pp. 39-48 (1990) (Garner Exhibit 25)" (Paper No. 22 at 7 ¶11).

f. "Clark [WO 88/00239] (Garner Exhibit 31)...published on January 14, 1988" (Paper No. 22 at 11 ¶16(c)).

g. "Farrell et al., Blood, 74, p. 55a (1989) (Garner Exhibit 26)" (e.g., Paper No. 22 at 7 ¶12).

h. "Farrell et al., Biochemistry, 30, pp. 9414-9420 (1991) (Garner Exhibit 6)"
(e.g., Paper No. 22 at 6 ¶9).

i. "Greenberg et al., Proc. Natl. Acad. Sci., 88, pp. 8327-8331 (1991)
(Garner Exhibit 7)" (Paper No. 22 at 12 ¶18).

j. "Hennighausen, Protein Expression and Purification, 1, pp. 3-8 (1990)
(Garner Exhibit 29)" (Paper No. 22 at 13 ¶19).

k. "Hurtley et al., Ann. Rev. Cell. Biol., 5, pp. 277-307 (1989) (Garner
Exhibit 34)" (Paper No. 22 at 14 ¶24).

l. "Meade [U.S. Patent 4,873,316] (Garner Exhibit 30)...patented on October
10, 1989" (e.g., Paper No. 22 at 10 ¶16(a)).

m. "Nicoll et al., Life Sciences, pp. 993-1001 (1965) (Garner Exhibit 32)"
(Paper No. 22 at 14 ¶22).

n. "Prunkard et al., *High Level Secretion of Recombinant Human Fibrinogen
in BHK Cells is Limited by a Post-Transcriptional Process* (Poster No. H123 presented at the
Keystone Symposium on Genetic and In Vitro Analysis of Cell Compartmentalization, Taos,
New Mexico, February 8-14, 1993), J. Cell Biochem., Supplement 17C, Poster No. H123
(February 8, 1993) (Garner Exhibit 35)" (e.g., Paper No. 22 at 7 ¶12).

o. "Rixon et al., Biochemistry, 22, pp. 3237-3244 (1983) (Garner
Exhibit 22)" (Paper No. 22 at 7 ¶11).

p. "Rosen [U.S. Patent 5,304,489] (Garner Exhibit 37)...patented on April 19, 1994, based on an application filed October 24, 1990" (Paper No. 22 at 11 ¶16(b) (footnote omitted)).

q. "Roy et al., J. Biol. Chem., 266, pp. 4758-4763 (1991) (Garner Exhibit 5)" (Paper No. 22 at 7 ¶12).

r. "Storb et al., J. Exp. Med., 164, pp. 627-641 (1986) (Garner Exhibit 9)" (Paper No. 22 at 12 ¶18).

4. The decision (Paper No. 110) relies on the following prior art: Clark (at 17), Greenberg (at 17), Hennighausen (at 11), Meade (at 12), and Rosen (at 17).

5. The decision also discusses the significance of the following Velander references provided in opposition:

a. T. Burdon et al., "Over-expression of an endogenous milk protein gene in transgenic mice is associated with impaired mammary alveolar development and a *milchlos* phenotype", 36 Mechs. Dev. 67-74 (1991) (Paper No. 110 at 15).

b. P.A. Furth et al., "The variability in activity of the universally expressed human cytomegalovirus immediate early gene 1 enhancer/promoter in transgenic mice", 19 Nucleic Acids Res. 6205-08 (1991) (Paper No. 110 at 15).

c. K. Gordon et al., "Production of human tissue plasminogen activator in transgenic mouse milk", 5 Biotech. 1183-87 (1987) (Paper No. 110 at 16).

d. L.-M. Houdebine, "Minireview: Production of pharmaceutical proteins from transgenic animals", 34 J. Biot. 269-87 (1994) (Paper No. 110 at 14).

e. A. Shamay et al., "Expression of the whey acidic protein in transgenic pigs impairs mammary development", 1 Transgenic Res. 124-32 (1992) (Paper No. 110 at 15).

f. R.J. Wall et al., "High-level synthesis of a heterologous milk protein in the mammary glands of transgenic swine", 88 Proc. Nat'l Acad. Sci. (USA) 1696-1700 (1991) (Paper No. 110 at 15).

g. C.B.A. Whitelaw et al., "Targeting expression to the mammary gland: intronic sequences can enhance the efficiency of gene expression in transgenic mice", 1 Transgenic Res. 3-13 (1991) (Paper No. 110 at 15).

6. Patentability of Velander's involved claims was determined on the basis of its involved claim 65 with the other involved claims standing or falling with claim 65 (Paper No. 110 at 6).

7. The decision contained the following fact findings (footnotes omitted) (Paper No. 110 at 8) based on the statement of material facts in Garner preliminary motion 2 (Paper No. 22):

m. As of the critical date, biocompetent human fibrinogen had been produced using cultured mammalian cells transfected with the cDNAs encoding the three [fibrinogen] chains (Paper No. 22 at 7, ¶12 (uncontested)).

n. As of the critical date, several introduced proteins had been produced in the milk of transgenic mammals. The prior art included teachings or suggestions for the production of blood and serum proteins in the milk of transgenic mammals (Paper No. 22 at 10-11, ¶16).

8. The references cited in ¶16 of the statement of facts are Meade, Rosen, and Clark.

9. Procedurally, the only actions remaining to Velander were a request for reconsideration or judicial review (Paper No. 110 at 35). Velander requested and received extensions in time to permit it to file its request for reconsideration (Paper No. 115).

10. VELANDER REQUEST FOR RECONSIDERATION (of the Decision on Preliminary Motion No. 2) was filed on 29 November 2001. Velander's request (Paper No. 118 at 2):

In particular, ...submits that the Board misapprehended or overlooked its duty to specify the prior art publications on which it based its conclusion of obviousness.

11. The request further states that "the Board did not point to the references supporting a motivation to combine the prior art" (Paper No. 118 at 4).

12. Finally, according to the request, "the Board did not point to any prior art publication that could be construed as evidencing the reasons for expecting success in the transgenic production of fibrinogen" (Paper No. 118 at 5). Velander notes the board's discussion of the Hennighausen review and the Meade patent, but argues that they relate "to motivation rather than success" (Paper No. 118 at 5).

13. The decision identifies reasonable expectation of success as a key issue in the obviousness determination (Paper No. 110 at 9 ¶s) and considers the question at length (¶¶s-bbb). Among other findings, the decision notes the encouraging tone of the Hennighausen review (¶¶y & z), particularly for blood proteins. The decision also notes the difficulties that the Hennighausen review identifies, but the decision explains why it does not consider those difficulties as indicating no reasonable expectation of success.

14. Garner opposes, in part, on the basis that the request is a collateral attack on the sufficiency of the references (and by implication, Garner's preliminary motion). According to Garner, Velander's opportunity to raise these concerns came when Velander filed its opposition.

C. DISCUSSION

1. The references on which Garner's motion was granted

It is well-settled that a party is entitled to a positive recitation of the prior art underlying a rejection. In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). In a preliminary motion, however, this recitation is provided in the first instance by the movant's motion. If Garner's preliminary motion fails to set forth a prima facie case for unpatentability, the time for Velander to raise that concern is in the opposition to that motion, not in a request for reconsideration.

Garner's preliminary motion necessarily defines the universe of prior art references that the board could base its decision granting the motion without resort to a new ground of unpatentability (37 C.F.R. § 1.641) or to official notice (37 C.F.R. § 1.671(c)(3); Fed. R. Evid. 201). Thus, at the outset, the decision granting Garner's preliminary motion was limited to relying on Behringer (Garner Exhibit 33), Burdon (Garner Exhibit 8), Chung (Garner Exhibit 23), Chung (Garner Exhibit 24), Chung (Garner Exhibit 25), Clark (Garner Exhibit 31), Farrell (Garner Exhibit 26), Farrell (Garner Exhibit 6), Greenberg (Garner Exhibit 7), Hennighausen, (Garner Exhibit 29), Hurtley (Garner Exhibit 34), Meade (Garner Exhibit 30), Nicoll (Garner Exhibit 32), Prunkard (Garner Exhibit 35), Rixon (Garner Exhibit 22), ~~Reagan~~ (Garner Exhibit 37), Roy (Garner Exhibit 5), and Storb (Garner Exhibit 9). Of these, the

decision focuses on Clark, Greenberg, Hennighausen, Meade, and Rosen, as well as the testimony provided in support of the motion on how the prior art should be understood. The decision also takes into account evidence that Velander provided for all it fairly indicated about what a person having ordinary skill in the art would have understood from the Garner-provided prior art. Hence, the decision was based on a consideration of all of the cited prior art, with particular reference to Clark, Greenberg, Hennighausen, Meade, and Rosen.

2. The motivation to combine

Although Velander submits that the decision did not identify any motivation to combine the teachings in the prior art (Paper No. 118 at 4), Velander's request concedes that both Hennighausen and Meade were cited as providing motivation to move from cell-culture production of pharmaceutical proteins, and particularly blood serum proteins, to transgenic animal milk production (at 5). The decision includes an uncontested finding that making biocompetent human fibrinogen in cultured mammalian cells transfected with fibrinogen cDNAs was known in the art. The decision provides express motivation for the main difference between the prior art (production of fibrinogen in cell cultures) and the subject matter of Velander's claim 65 (production of fibrinogen in transgenic mammal milk). Velander's request does not point to any other difference where motivation is lacking.

3. The likelihood of success

Velander argues that the decision does not identify any reasonable expectation of success in the art. The case law only requires a reasonable expectation, not absolute predictability. In re O'Farrell, 853 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). The decision notes the

encouragement provided in the Hennighausen review and the Meade patent. It also notes the problems cited in Hennighausen and in Velander's exhibits, but finds on balance that they provide a reasonable expectation of success. Although Velander dismisses the discussion of Hennighausen and Meade as being merely about motivation, motivation and expectation of success are logically associated and thus it should not be surprising that they are discussed together.

The Hennighausen review in particular touts the use of transgenic animals for the very class of pharmaceutical proteins (blood serum proteins) to which fibrinogen belongs. Similarly, Meade obtained a patent for production of a blood protein in transgenic mammal milk. Cf. In re Inland Steel Co., 265 F.3d 1354, 1364, 60 USPQ2d 1396, 1404 (Fed. Cir. 2001) (success for similar problems suggests likelihood of success). The problems identified in the art are not presented as insurmountable or unique to blood proteins. Taken as a whole, Hennighausen and Meade provide a prima facie expectation of success. Velander's focus in opposition on variability is misdirected since it suggests that a successful production of fibrinogen via milk will be hard and expensive, but not unexpected. See In re Longi, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985) (variability does not preclude obviousness).

D. CONCLUSION

The findings Velander submits are lacking in the decision on motions are in fact present as explained above and in Garner's opposition to Velander's request. Velander has not justified relief from the order granting Garner preliminary motion 2, which held all of Velander's involved claims to be unpatentable.

E. ORDER

Upon consideration of Velander's request for reconsideration, it is—

ORDERED that relief from the DECISION ON MOTIONS (Paper No. 110) be DENIED;

and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative record of Garner's 5,639,940 patent and Velander's 08/443,184 application.

m.e.K

FRED E. McKELVEY
Senior Administrative Patent Judge

Richard E. Schaffer

RICHARD E. SCHAFER
Administrative Patent Judge

Richard Torczon

RICHARD TORCZON
Administrative Patent Judge

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INTERFERENCE
TRIAL SECTION

Interference No. 104,242
Garner v. Velander

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